

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) P-5808/1	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on _____ Signature _____ Typed or printed name _____		Application Number 10/664,715	
		Filed September 18, 2003	
		First Named Inventor Dimitrios Manoussakis	
		Art Unit 1797	Examiner Patricia Kathryn Wright

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

/Mark Lindsey/

Signature

Mark Lindsey

Typed or printed name

attorney or agent of record.

Registration number 52,515

201-847-6262

Telephone number

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____

June 29, 2009

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

<input type="checkbox"/>	*Total of _____ forms are submitted.
--------------------------	--------------------------------------

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	10/664,715	Confirmation No.:	4404
Applicant(s)	Dimitrios Manoussakis	Examiner:	P. Kathryn Wright
Filed:	September 18, 2003	Docket:	P-5808/1
Group Art Unit:	1743	Customer No.:	26253

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRESENTATION OF PRE-APPEAL BRIEF REASONS FOR REVIEW

A complete listing of the current pending claims can be found in Applicant's Response dated February 20, 2009 to the Office Action dated November 21, 2008.

Claims Rejections – 35 USC § 102

Claims 14, 16-18 and 21-32 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 4,350,593 to Kessler ("Kessler").

Applicants respectfully traverse this rejection.

Of the claims rejected, claim 14 is independent, with the remaining claims dependent thereon.

Claim 14 recites among other things:

a thixotropic gel in contact with a portion of the inner wall, wherein the thixotropic gel comprises continuous first and second regions, the first region located at or adjacent to the lower end, and the second region extending upward from a portion of the first region, wherein the first region comprises an imaginary upper boundary at which the first region exhibits 360° circumferential contact with the inner wall, and wherein the first region comprises at least about 80 vol.% of the thixotropic gel.

Kessler discloses a blood collection and separation device which uses a non-newtonian gel of a specified composition as a barrier which overcomes a high yield stress by having a gel upper surface which is not perpendicular to the longitudinal axis of the device. This arrangement allegedly causes immediate flow of the gel under normal centrifugal forces in order to form a barrier as soon as possible during centrifugation [see Col. 4 lines 19-38].

Initially, applicants submit that Kessler clearly does not explicitly anticipate claim 14.

MPEP section 2131 on Anticipation — Application of 35 U.S.C. 102(a), (b), and (e) [R-1]: **TO ANTICIPATE A CLAIM, THE REFERENCE MUST TEACH EVERY ELEMENT OF THE CLAIM**

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053(Fed. Cir. 1987).

Kessler clearly fails to disclose at least the claimed feature of the first region comprising at least about 80 vol.% of the thixotropic gel. The Examiner’s arguments appear to adopt this view as well, and thus rely instead on inherency.

According to well-established law, in order for a prior art reference to amount to an inherent anticipation of a claim, all the elements of the claim must necessarily, inevitably and always result from the prior art disclosure; mere possibilities or probabilities are not sufficient. *See Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1269, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553-54, 220 U.S.P.Q. 303, 313-14 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 325-26 (C.C.P.A. 1981); *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F.Supp. 1278, 1295 n.12, 6 U.S.P.Q.2d 1065, 1076-77 n.12 (D. Del. 1987), *aff’d*, 865 F.2d 1247, 9 U.S.P.Q.2d 1461 (Fed. Cir. 1989); *Hughes Aircraft Co. v. U.S.*, 8 U.S.P.Q.2d 1580, 1583 (Ct. Cl. 1988); *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1463-64 (B.P.A.I. 1990); *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1788-89 (B.P.A.I. 1987).

Thus, it is not sufficient that a teaching of a prior art reference could yield a result that would anticipate the claim against which the prior art reference is applied; instead, to be anticipatory under the doctrine of inherency, the teaching of the prior art reference must inevitably lead to the result.

The Examiner makes three basic arguments in the final Office Action dated March 27, 2009, in support of inherent anticipation:

(1) "Kessler teaches a thixotropic gel 22 located inside at the closed lower end of the container contacting a portion of the inner wall (col. 1, line 56- col. 2, line 2; col. 3, line 54- col. 4, line 6; see also Figs. 2-3). Therefore, since the claimed and prior art gels are identical or substantially identical in structure or composition they must necessarily exhibit the same rheological properties under the same conditions. That is, the first region of the gel of Kessler inherently comprises:

a first region with at least about 80 vol. % of the gel (claim 14),"

(2) "In addition, Applicant's specification recites the desired geometry of gel may be provided by disposing the thixotropic gel into the tube using a nozzle, then centrifuging the tubes at a particular angle and speed to provide the desired geometry, see paragraph [0035]. Note the particular angle and speed is not disclosed in Applicant's original specification. Similarly, Kessler teaches filling container with a barrier material (same gel as claimed) such that the barrier material 22 is disposed with the surface 23 forming other than a plane perpendicular to the axis A of the tube 12, see Fig. 2. Kessler teaches the manner of making the invention includes introducing the barrier material 22 into the container, then testing for its bleed and yield stress (see Example 1). This test comprises storing the assembly 10 (i.e., thixotropic gel in the container 12) for a period of time and then ultra-centrifuging an aliquot of the barrier material 22.

Thus, the gel of Kessler must inevitably comprise the geometry recited in the claims, since the claimed gel, and that of Kessler, are introduced into the container and centrifuged in the same manner."

(3) "Furthermore, Kessler recognizes the importance of the vast majority of the gel be at or near the bottom of the tube with a portion of the gel extending upward onto the inside surface so as overcome the yield stress of the barrier material and cause gel movement at the earliest possible stage of centrifugation so as to avoid rupture of cellular blood components."

As to argument (1), Applicants respectfully point out that claim 14 is directed to a specific geometry of a thixotropic gel in a container, and not a gel composition/structure, nor rheological properties of a gel. Applicants have discovered that the specific geometry or shape of a gel has a significant effect of the movement of the gel during centrifugation and on the separation performance of the gel barrier, thus a common gel having different geometries within two tubes will have different movement properties during a common centrifugation. The arrangement of the gel in Kessler does not disclose, implicitly or explicitly, the claimed gel geometry. The fact that the reference teaches a gel, and teaches the gel arranged with a non-perpendicular top surface does not necessarily lead to the claimed invention.

As to argument (2), Applicants respectfully dispute that the methods of gel introduction of Kessler and the instant specification are so similarly as to necessarily lead to an identical result. Differences, for example, include:

- a) Kessler fails to disclose the conditions under which upper surface 23 is formed at a plane other than a plane perpendicular to the axis A of the tube 12, (see Fig. 2).
- b) Example 1 of Kessler discloses the synthesis of an embodiment of barrier material 22 and not the conditions used to produce a specific gel geometry in a tube.
- c) Kessler discloses that the test for bleed and yield stress does not comprise storing the assembly 10 (i.e., thixotropic gel in the container 12) for a period of time, but comprises the ultra-centrifugation of an aliquot of barrier material to accelerate bleed and sedimentation processes to predict how a barrier material will perform after assembly 10 is stored under normal storage conditions 1 to 2 years in storage (see Col. 7 lines 38-52).

Thus, this argument also fails to show inherency.

As to argument (3), even if Kessler recognizes a particular approach to gel configuration, a mere recognition cannot constitute inherent anticipation. The fact remains that Kessler does not disclose, explicitly or implicitly, the claimed gel configuration.

For these reasons, applicants submit that independent claim 14 and dependent claims 16-18 20-24, 26-28 and 30-32, are not anticipated by the Kessler reference.

Conclusion

In view of the remarks herein, applicants submit the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact applicants' agent at the telephone number set forth below.

Respectfully submitted,

/Mark Lindsey/

Mark Lindsey
Registration No. 52,515
Agent for Applicant(s)
201 847 6262

Dated: June 29, 2009.
Becton, Dickinson and Company
1 Becton Drive, MC110
Franklin Lakes, New Jersey 07417-1880

Doc# 157617v1